

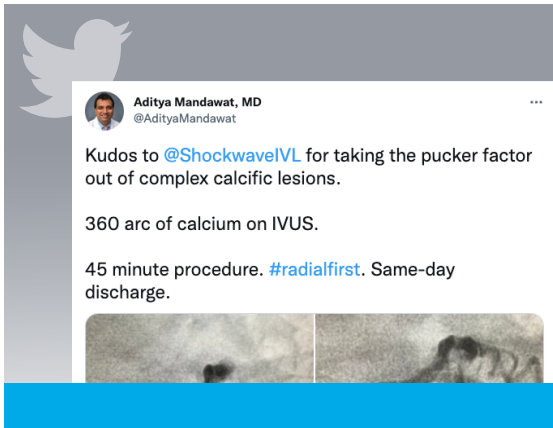
PulsePoint

Shockwave Quarterly Newsletter to Keep Your Finger on the Pulse of IVL News, Trends, & Evidence

Temps are Coolin' But Shockwave is Heatin' Up

Shockwave had a sizzling summer but even as the temperature drops and the leaves change, we aren't cooling down just yet! The recent quarter brought excitement around our podcast, ChalkTalk, which really took off as we spoke with calcium experts, leading physicians, and even one of the co-founders of IVL. It was bittersweet when we concluded the

[CalciumMasterclass.com](#) series but with conference season in full swing, we've seen excellent presentations and symposiums on IVL across the globe. Most notably, the results from the first 752 patients in the [Disrupt PAD III Observational Study](#) were presented at VIVA '21. There's still lots more to share before we wrap up the year, don't miss the pulse!



#1 Most Engaging Twitter Post from Q3

[SEE THE POST](#)

NEW IVL PUBLICATIONS



Cardiovascular Revascularization Medicine

First United States experience with Rota-Shock: A case series

Dr. Gautam Kumar

[Read More >](#)

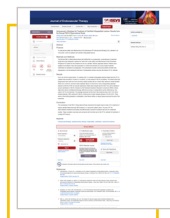


Journal of Interventional Cardiology

Intravascular Lithotripsy for Calcium Modification in Chronic Total Occlusion Percutaneous Coronary Intervention

Dr. Margaret McEntegart

[Read More >](#)



Journal of Endovascular Therapy

Intravascular Lithotripsy for Treatment of Calcified Infrapopliteal Lesions: Results from the Disrupt PAD III Observational Study

Dr. George Adams

[Read More >](#)



Top 3 Blog Posts from Q3

1



CHALK

ChalkTalk Episode #3

"Eureka Moment" with John Adams (IVL Creator) & Dr. Ziad Ali

SHOCKWAVE IVL

2



CHALK

ChalkTalk Episode #4

Calcium Masterclass Q&A with Prof. James Spratt

SHOCKWAVE IVL

3



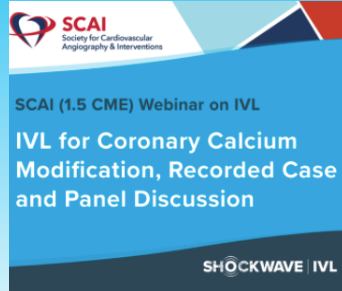
CHALK

ChalkTalk Episode #5

Q&A with Paul Higginbottom, UK & France Director of Sales

SHOCKWAVE IVL

TOP 3 CONGRESS & DATA PRESENTATION HIGHLIGHTS



SCAI: Coronary IVL Presentations for CME

Learn about Coronary IVL and get CME credits. SCAI is offering a great recorded case and discussion for 1.5 credits featuring a panel of Shockwave IVL experts.

[Watch Now >](#)

CIRSE 2021

Cracking the Myths around Eccentric Calcification

Prof. Andrew Holden, MD
Auckland, New Zealand

SHOCKWAVE IVL

Cracking the Myths around Eccentric Calcification

Watch Prof. Andrew Holden's presentation from CIRSE21 as he walks you through IVL's eccentric vs concentric lesion data subset from the PAD III Observational Study.

[Watch Now >](#)

SHOCKWAVE IVL

Late Breaking News at VIVA21:

Real World Calcium. Consistent Results.

Dr. Ehrin Armstrong
Medical Director, Adventist Heart and Vascular Institute

VIVA LBCT OS750

Dr. Ehrin Armstrong presented the interim results from the first 752 patients in the Disrupt PAD III Observational Study.

[Watch Now >](#)

SHOCKWAVE IN THE NEWS



Dr. Nadia Sutton Highlights the Need for Coronary IVL

[Read More >](#)



Dr. Evan Shlofmitz on Calcium Algorithms

[Read More >](#)



IVL: Not an Eccentric Option for Eccentric Calcium With Profs. Holger Nef and Carlo DiMario

[Read More >](#)

#1 FEATURED VIDEO IN Q3



Class 10 (Live Case) - The Deep Dive on Calcium, Bringing it all Together

[Watch the Recap >](#)

UPCOMING NEWS



TCT 2021

[Register Now >](#)



VEITH 2021

[Register Now >](#)

Important Safety Information

CORONARY ISI:

Rx only

Indications for Use—The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2 Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

Contraindications—The Shockwave C2 Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries.

Warnings— Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy.

Precautions— Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion.

Potential adverse effects consistent with standard based cardiac interventions include— Abrupt vessel closure – Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or non-emergency coronary artery bypass surgery-Emergency or non-emergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)-Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever-Myocardial Infarction-Myocardial Ischemia or unstable angina-Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke-Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm.

Risks identified as related to the device and its use: Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture.

Prior to use, please reference the Instructions for Use for more information on warnings, precautions and adverse events.

<https://shockwavemedical.com/IFU>

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C² instructions for use containing important safety information.

PERIPHERAL ISI:

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Indication for Use – The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. Not for use in the coronary or cerebral vasculature.

Contraindications – Do not use if unable to pass 0.014 guidewire across the lesion • Not intended for treatment of in-stent restenosis or in coronary, carotid, or cerebrovascular arteries.

Warnings – Only to be used by physicians who are familiar with interventional vascular procedures • Physicians must be trained prior to use of the device • Use the Generator in accordance with recommended settings as stated in the Operator's Manual

Precautions – Use only the recommended balloon inflation medium • Appropriate anticoagulant therapy should be administered by the physician • Decision regarding use of distal protection should be made based on physician assessment of treatment lesion morphology

Adverse Effects – Possible adverse effects consistent with standard angioplasty include: • Access site complications • Allergy to contrast or blood thinners • Arterial bypass surgery • Bleeding complications • Death • Fracture of guidewire or device • Hypertension/Hypotension • Infection/sepsis • Placement of a stent • Renal failure • Shock/pulmonary edema • Target vessel stenosis or occlusion • Vascular complications. Risks unique to the device and its use: • Allergy to catheter material(s) • Device malfunction or failure • Excess heat at target site

Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions, and adverse events. www.shockwavemedical.com